General

Guideline Title

Evidence-based guideline update: steroids and antivirals for Bell palsy: report of the Guideline Development Subcommittee of the American Academy of Neurology.

Bibliographic Source(s)

Gronseth GS, Paduga R. Evidence-based guideline update: steroids and antivirals for Bell palsy: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2012 Nov 27;79(22):2209-13. [19 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Grogan PM, Gronseth GS. Practice parameter: Steroids, acyclovir, and surgery for Bell's palsy (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2001 Apr 10;56(7):830-6. [25 references]

Recommendations

Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (Class I-IV) are provided at the end of the "Major Recommendations" field.

Recommendations

For patients with new-onset Bell palsy, oral steroids should be offered to increase the probability of recovery of facial nerve function (Level A).

For patients with new-onset Bell palsy, antivirals (in addition to steroids) might be offered to increase the probability of recovery of facial function (Level C). Patients offered antivirals should be counseled that a benefit from antivirals has not been established, and, if there is a benefit, it is likely that it is modest at best (risk difference [RD] <7%).

Putting the Evidence into A Clinical Context

Although there is strong evidence that steroid use increases the probability of good facial functional recovery in patients with Bell palsy, it does not necessarily follow that all patients with Bell palsy need to take steroids. For example, it would be reasonable for a clinician to opt not to use steroids in a patient with brittle diabetes mellitus. Other comorbidities potentially requiring further consideration include morbid obesity, osteopenia, and a prior history of steroid intolerance.

The authors found limited evidence of the efficacy of steroids and antivirals in important Bell palsy subgroups, including those with a lower

probability of recovery because of severe palsy at presentation and those with possible zoster sine herpete. Such studies are particularly important relative to the efficacy of the addition of antivirals to steroids given the lack of evidence for moderate efficacy in the "typical" patient with Bell palsy.

Authors of one Class I study performed a preplanned subgroup analysis on patients with severe palsy at presentation defined by a Sunnybrook Scale score of 0 to 25. This analysis showed no significant difference in 12-month recovery rates between patients treated with prednisolone alone as compared with patients treated with prednisolone plus valacyclovir (RD 0.2% favoring valacyclovir 95% confidence intervals [CI], -18% to 17.6%). However, the analysis lacked the statistical precision to exclude an important beneficial effect (or harm) from the addition of valacyclovir. A Class IV study observed a significant improvement in recovery (RD 26.6%) between patients with severe Bell palsy treated with prednisone alone and patients with severe Bell palsy treated with prednisone plus famciclovir (House-Brackmann Scale score of 5 or 6). This study had a high risk of bias because of pseudorandomized treatment allocation and unmasked outcome assessment.

Relative to zoster sine herpete, a Class IV study observed no significant difference in recovery after treatment with prednisolone alone as compared with treatment with prednisolone plus valacyclovir in a subgroup of 28 patients with evidence of zoster reactivation (hazard ratio for recovery 1.6 favoring prednisolone plus valacyclovir, 95% CI 0.4 to 6.1). The small sample size and high risk of bias make this observation inconclusive.

These studies in aggregate do not provide strong evidence to identify subgroups of patients that might benefit more or less from treatment.

Because the studies included only patients presenting early after palsy onset, it is difficult to determine the effect of steroid or antiviral treatment in patients presenting later in the course of their illness (e.g., 1 week after the onset of facial weakness). Likewise, although it seems reasonable to assume that an equivalent dose of alternative steroids would also be effective, decisions regarding alternative steroid dosing regimens necessarily require clinician judgment.

Definitions:

Classification of Evidence

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required:

a. Concealed allocation
b. Primary outcome(s) clearly defined
c. Exclusion/inclusion criteria clearly defined
d. Adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias
e. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-e above OR a randomized controlled trial (RCT) in a representative population that lacks one criteria a-d.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement*.

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

*Objective outcome measurement: An outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

Strength of Recommendations

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)**

B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

**In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome

> 5 and the lower limit of the confidence interval is > 2).

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Bell palsy

Note: Bell palsy is an acute, peripheral facial paresis of unknown cause.

Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

Clinical Specialty

Neurology

Intended Users

Physician Assistants

Physicians

Guideline Objective(s)

To review evidence published since the 2001 American Academy of Neurology (AAN) practice parameter regarding the effectiveness, safety, and tolerability of steroids and antiviral agents for Bell palsy

Target Population

Patients with Bell palsy

Interventions and Practices Considered

1. Steroids
2. Antiviral agents (acyclovir, famciclovir, valacyclovir)

Major Outcomes Considered

Recovery of facial nerve function

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The authors searched Medline for articles published from June 2000 through January 2012 using the term "Bell's palsy" and the sensitive, therapeutic clinical filter (see appendix e-3 of the original guideline document for the specific search strategy employed). The Cochrane Database of Systematic Reviews and Controlled Clinical Trials was also searched. A secondary search of the references of selected articles and review articles (including Cochrane systematic reviews) was performed to identify studies missed by our search strategy.

The search strategy identified 340 citations. The authors reviewed the full text of 38 potentially relevant articles. Nine articles fulfilled the inclusion criteria.

Number of Source Documents

9

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classification of Evidence

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required:

a. Concealed allocation
b. Primary outcome(s) clearly defined
c. Exclusion/inclusion criteria clearly defined
d. Adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias
e. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-e above OR a randomized controlled trial (RCT) in a representative population that lacks one criteria a-d.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement*.

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

*Objective outcome measurement: An outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The titles and abstracts of the identified citations were reviewed for relevance to the clinical question. The full text of potentially relevant articles was retrieved and included in the analysis if these studies determined facial functional outcomes after at least 3 months of follow-up in at least 20 patients with new-onset Bell palsy. The authors included only controlled trials with prospective data collection comparing outcomes in patients treated with steroids or antiviral agents with patients not treated with these medications. Both authors independently reviewed articles and completed data abstraction. Discrepancies were resolved through discussion.

Facial functional recovery was defined as "good" or "complete" using the same criteria used in the 2001 practice guideline. The quantitative measure of the treatment effect employed was the difference in the proportion of patients attaining complete or good facial recovery in the treatment group relative to the comparative group (i.e., the risk difference [RD]). In studies using the House and Brackmann facial function scoring system, the authors considered an outcome of grade I or II a good recovery. When comparing the proportion of patients recovering complete facial function, we considered an outcome of grade I a complete recovery. The measure of statistical precision used was the 95% confidence intervals (CIs) of the RD, and an RD $\geq 10\%$ was considered clinically meaningful. The frequency and severity of the adverse events (AEs) from the treatments employed were also abstracted.

Studies were rated for their risk of bias using the AAN 4-tiered classification of evidence scheme for therapeutic studies (see appendix e-4 of the original guideline document). Studies from the original guideline were re-rated using the updated classification of evidence scheme. The strength of practice recommendations was linked to the strength of evidence (see appendix e-5 of the original guideline document).

For the purpose of formulating conclusions and recommendations, we used the term "steroids" regardless of the specific type, dose, and route of steroids used in the reviewed studies. Likewise, we used the term "antiviral agents" regardless of the specific type of agent used in the reviewed studies.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The American Academy of Neurology (AAN) Guideline Development Subcommittee (see appendices e-1 and e-2 of the original guideline document) systematically reviewed studies that were considered relevant to this question: For patients with new-onset Bell palsy, does treatment with steroids or antiviral agents (acyclovir, famciclovir, valacyclovir) improve facial functional recovery?

Conclusion and recommendations were linked to the strength of the evidence (see the "Rating Scheme for the Strength of the Recommendations" field).

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome > 5 and the lower limit of the confidence interval is > 2).

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafts of the guideline have been reviewed by at least three American Academy of Neurology (AAN) committees, a network of neurologists, *Neurology* peer reviewers and representatives from related fields.

This guideline was approved by the AAN Guideline Development Subcommittee on January 21, 2012; by the AAN Practice Committee on May 14, 2012; and by the AAN Board of Directors on August 21, 2012.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate treatment and management of patients with Bell palsy

Potential Harms

Side Effects of Steroids and Antiviral Agents

- All studies reported adverse events (AEs) from steroids. In general, these were minor and temporary. The most common AEs reported were insomnia and dyspepsia.
- None of the studies demonstrated a significant increase in any AE for patients randomized to an antiviral agent.

Contraindications

Contraindications

Groups potentially requiring further consideration before the use of steroids include patients with brittle diabetes mellitus, morbid obesity, osteopenia and those with prior history of steroid intolerance.

Qualifying Statements

Qualifying Statements

This statement is provided as an educational service of the American Academy of Neurology (AAN). It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved. The clinical context section is made available in order to place the evidence-based guideline(s) into perspective with current practice habits and challenges. Formal practice recommendations are not intended to replace clinical judgment.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Gronseth GS, Paduga R. Evidence-based guideline update: steroids and antivirals for Bell palsy: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2012 Nov 27;79(22):2209-13. [19 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2001 Apr (revised 2012 Nov)

Guideline Developer(s)

American Academy of Neurology - Medical Specialty Society

Source(s) of Funding

American Academy of Neurology (AAN)

Guideline Committee

Guideline Development Subcommittee of the American Academy of Neurology

Composition of Group That Authored the Guideline

Guideline Authors: Gary S. Gronseth, MD, FAAN & Remia Paduga, MD

Guideline Development Subcommittee (GDS) members: John D. England, MD, FAAN (Chair); Cynthia Harden, MD (Vice-Chair); Melissa Armstrong, MD; Eric Ashman, MD; Misha-Miroslav Backonja, MD; Richard L. Barbano, MD, PhD, FAAN; Diane Donley, MD; Terry Fife, MD, FAAN; David Gloss, MD; John J. Halperin, MD, FAAN; Cheryl Jaigobin, MD; Andres M. Kanner, MD; Jason Lazarou, MD; Steven R. Messé, MD, FAAN; David Michelson, MD; Pushpa Narayanaswami, MD, MBBS; Anne Louise Oaklander, MD, PhD, FAAN; Tamara Pringsheim, MD; Alexander Rae-Grant, MD; Michael Shevell, MD, FAAN; Theresa A. Zesiewicz, MD, FAAN; Jonathan P. Hosey, MD, FAAN (Ex-Officio); Stephen Ashwal, MD, FAAN (Ex-Officio); Deborah Hirtz, MD, FAAN (Ex-Officio)

Financial Disclosures/Conflicts of Interest

Conflict of Interest

The American Academy of Neurology (AAN) is committed to producing independent, critical and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. Drafts of the guideline have been reviewed by at least 3 AAN committees, a network of neurologists, Neurology peer reviewers and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at www.aan.com .

Disclosures

G. Gronseth serves as an editorial advisory board member of Neurology Now; served on a speakers' bureau for Boehringer Ingelheim; and receives honoraria from Boehringer Ingelheim and the American Academy of Neurology. R. Paduga reports no disclosures. Go to Neurology.org for full disclosures.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Grogan PM, Gronseth GS. Practice parameter: Steroids, acyclovir, and surgery for Bell's palsy (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2001 Apr 10;56(7):830-6. [25 references]

Guideline Availability

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the AAN Web site [   ].

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 201 Chicago Avenue South, Minneapolis, MN 55415.

Availability of Companion Documents

The following are available:

- Evidence-based guideline update: Steroids and antivirals for Bell palsy. Data supplement (e-appendices). Available from the American Academy of Neurology (AAN) Web site [   ].
- Update: Steroids and antivirals for Bell palsy. AAN summary of evidence-based guideline for clinicians. St. Paul (MN): American Academy of Neurology. 2012. 1 p. Available in Portable Document Format (PDF) from the AAN Web site [   ].
- Update: Steroids and antivirals for Bell palsy. Case presentation. St. Paul (MN): American Academy of Neurology. 2012. 5 p. Available in PDF from the AAN Web site [   ].
- Update: Steroids and antivirals for Bell palsy. Slide presentation. St. Paul (MN): American Academy of Neurology. 2012. Available from the AAN Web site [   ].
- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Available from the AAN Web site [   ].

Patient Resources

The following is available:

- Bell's palsy: Treatment with steroids and antiviral drugs. AAN summary of evidence-based guideline for patients and their families. St. Paul (MN): American Academy of Neurology. 2012. 2 p. Available in Portable Document Format (PDF) from the American Academy of Neurology (AAN) Web site [   ].

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This summary was completed by ECRI on February 12, 2002. The information was verified by the guideline developer as of March 29, 2002. This summary was updated by ECRI Institute on February 26, 2013.

Copyright Statement

This NGC summary is based on the original guideline, which is copyrighted by the American Academy of Neurology.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ,,¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.